The ADMIRAL Study

A clinical research study for children and adolescents with Dravet syndrome

Dravet syndrome is a severe and progressive genetic condition characterised by frequent, prolonged and uncontrolled seizures, beginning within the first year of life in an otherwise healthy child. Dravet syndrome is difficult to treat and there is little chance of recovery. The ADMIRAL Study, conducted by Stoke Therapeutics, will look at a potential new medicine called STK-001 for children and adolescents with Dravet syndrome.



About the ADMIRAL Study

The primary aim of the ADMIRAL Study is to see:

- How safe STK-001 is
- How multiple doses of STK-001 are tolerated by your child
- How STK-001 is taken up and broken down by the body when given as 3 doses

This study will also look at whether STK-001 affects the number of seizures and could improve quality of life for children and adolescents (from 2 to up to 18 years of age) with Dravet syndrome.

Why is the ADMIRAL Study important?

Dravet syndrome is one of the most drug-resistant forms of epilepsy. People with Dravet syndrome have approximately half of the normal levels of a protein, called Na_v1.1. Low levels of Na_v1.1 in the brain can lead to seizures and other symptoms of Dravet syndrome. The investigational medicine, STK-001, is designed to target the underlying cause of Dravet syndrome by helping the body make more Na_v1.1. It is hoped that the investigational medicine may reduce the symptoms of Dravet syndrome.

What will the ADMIRAL Study involve?

Up to 60 children and adolescents who are from 2 to up to 18 years of age will take part in this study in the United Kingdom. Participants will be in the study for approximately 10 to 12 months. The study will involve up to 12 planned visits to the study centre and 6 phone calls with a member of the study team.

During the ADMIRAL Study, children and adolescents will receive 3 injections of the investigational medicine in their spinal cord. Your child will need to stay at the hospital after receiving injections of the investigational medicine until the study doctor agrees that it is safe to leave.

What are the costs of participating in the ADMIRAL Study?

All investigational medicine, examinations and procedures that are required as part of the study will be paid for by the study sponsor, Stoke Therapeutics. Participants may be reimbursed for study-related travel expenses. The study doctor can give you details about how to get reimbursed.

Who can take part in the ADMIRAL Study?

To be eligible for the study, participants must be:

- From 2 to up to 18 years of age
- Have a confirmed diagnosis of Dravet syndrome

This is not a complete list of the study eligibility requirements. The study doctor will review the full list of requirements with you.

Want to know more?

If you are interested in learning more about the ADMIRAL Study, please visit:



www.Admiralstudy.com

You can also contact the ADMIRAL Study Team directly at:



admiral@iqvia.com

You can also check the study details on the ISRCTN registry using the number:



ISRCTN99651026

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